EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Yang Tang on 03/15/12.

The application has been amended as follows:

Claim 1 has been amended to read:

--"A composition comprising:

(a) nanoparticles of spray-dried glipizide or a salt thereof, wherein the glipizide nanoparticles have an effective average particle size of less than 2000 nm; and

(b) at least one surface stabilizer adsorbed on the surface of the glipizide nanoparticles;

wherein:

(i) the surface stabilizer is free of intermolecular cross-linkages;

(ii) the glipizide nanoparticles or a salt thereof is present in an amount of from about 99.5% to about 0.001%, by weight, based on the total combined weight of the glipizide nanoparticles or a salt thereof and at least one surface stabilizer, not including other excipients;

(iii) the at least one surface stabilizer is present in an amount of from about 0.5% to about 99.999% by weight, based on the total combined dry weight of the glipizide nanoparticles or a salt thereof and at least one surface stabilizer, not including other excipients;

(iv) upon administration to a mammal, the glipizide nanoparticles redisperse such that the nanoparticles have an effective average particle size of less than 2 microns; and

(v) the composition exhibits a C_{max} which is at least 50% greater than the C_{max} exhibited by a non-nanoparticulate glipizide composition when administered at the same dosage."--

Claim 3 has been amended to read:

--"The composition of claim 1, wherein the effective average particle size of the spray-dried glipizide nanoparticles is selected from the group consisting of less than 1900 nm, less than 1800 nm, less than 1700 nm, less than 1600 nm, less than 1500 nm, less than 1400 nm, less than 1300 nm, less than 1200 nm, less than 1100 nm, less than 1000 nm, less than 900 nm, less than 800 nm, less than 700 nm, less than 600 nm, less than 500 nm, less than 400 nm, less than 300 nm, less than 250 nm, less than 200 nm, less than 100 nm, less than 75 nm, and less than 50 nm."--

Claim 16 has been amended to read:

--"The composition of claim 1 further comprising at least one additional glipizide composition having an effective average particle size which is different from the effective average particle size of the spray-dried glipizide nanoparticles of (a)."--

Claim 18, line 1, the phrase "additionally" has been amended to "additional".

Claim 19, line 1, the phrase "additionally" has been amended to "additional".

Claim 21 has been amended to read:

--"The composition of claim 1, wherein upon administration the composition redisperses such that the spray-dried glipizide nanoparticles have an effective average particle size selected from the group consisting of less than 1900 nm, less than 1800 nm, less than 1700 nm, less than 1600 nm, less than 1500 nm, less than 1400 nm, less than 1300 nm, less than 1200 nm, less than 1100 nm, less than 1000 nm, less than 900 nm, less than 800 nm, less than 700 nm, less than 600 nm, less than 500 nm, less than 400 nm, less than 300 nm, less than 250 nm, less than 200 nm, less than 150 nm, less than 100 nm, less than 75 nm, and less than 50 nm."--

Claim 22 has been amended to read:

--"The composition of claim 1, wherein the composition redisperses in a biorelevant media such that the spray-dried nanoparticles have an effective average particle size of less than 2 microns."--

Claim 24 has been amended to read:

--"The composition of claim 22, wherein the composition redisperses in a biorelevant media such that the spray-dried glipizide nanoparticles have an effective average particle size selected from the group consisting of less than 1900 nm, less than 1800 nm, less than 1700 nm, less than 1600 nm, less than 1500 nm, less than 1400 nm, less than 1300 nm, less than 1200 nm, less than 1100 nm, less than 1000 nm, less than 900 nm, less than 800 nm, less than 700 nm, less than 600 nm, less than 500 nm, less than 400 nm, less than 300 nm, less than 250 nm, less than 200 nm, less than 150 nm, less than 100 nm, less than 75 nm, and less than 50 nm."--

Claim 36, second line, the term "about" immediately before the phrase "2000 mPa·s" has been deleted.

Claim 38 has been amended to read:

--"The composition of claim 36, wherein the viscosity of the dosage form is selected from the group consisting of less than 1/200, less than 1/100, less than 1/50, less than 1/25, and less than 1/10 of the viscosity of a liquid dosage form of a non-nanoparticulate composition of glipizide, at about the same concentration per ml of glipizide."--

Claim 39 has been amended to read:

--"The composition of claim 36, wherein the viscosity of the dosage form is selected from the group consisting of less than 5%, less than 10%, less than 15%, less

than 20%, less than 25%, less than 30%, less than 35%, less than 40%, less than 45%, less than 50%, less than 55%, less than 60%, less than 65%, less than 70%, less than 75%, less than 80%, less than 85%, and less than 90% of the viscosity of a liquid dosage form of a non-nanoparticulate composition of the glipizide, at about the same concentration per ml of glipizide."--

Claim 58 has been amended to read:

--"A method of treating diabetes in a subject in need thereof comprising administering to the subject an effective amount of a composition comprising:

(a) nanoparticles of a spray-dried glipizide or a salt thereof, wherein the glipizide nanoparticles have an effective average particle size of less than 2000 nm; and

(b) at least one surface stabilizer adsorbed on the surface of the glipizide nanoparticles,

wherein:

(i) the surface stabilizer is free of intermolecular cross-linkages;

(ii) the nanoparticle glipizide or a salt thereof is present in an amount of from about 99.5% to about 0.001%, by weight, based on the total combined weight of the nanoparticle glipizide or a salt thereof and at least one surface stabilizer, not including other excipients;

(iii) the at least one surface stabilizer is present in an amount of from about 0.5% to about 99.999% by weight, based on the total combined dry weight of the

nanoparticle glipizide or a salt thereof and at least one surface stabilizer, not including other excipients;

(iv) upon administration to a mammal, the glipizide nanoparticles redisperse such that the nanoparticles have an effective average particle size of less than 2 microns; and

(v) the composition exhibits a C_{max} which is at least 50% greater than the C_{max} exhibited by a non-nanoparticulate glipizide composition when administered at the same dosage."--

Claim 60 has been amended to read:

--"The method of claim 58, wherein the effective average particle size of the spray-dried glipizide nanoparticles is selected from the group consisting of less than 1900 nm, less than 1800 nm, less than 1700 nm, less than 1600 nm, less than 1500 nm, less than 1400 nm, less than 1300 nm, less than 1200 nm, less than 1100 nm, less than 1000 nm, less than 900 nm, less than 800 nm, less than 700 nm, less than 600 nm, less than 500 nm, less than 400 nm, less than 300 nm, less than 250 nm, less than 200 nm, less than 100 nm, less than 75 nm, and less than 50 nm."--

Claim 74, line 1, the phrase "additionally" has been amended to "additional".

Claim 75, line 1, the phrase "additionally" has been amended to "additional".

Claims 7, 8, 20, 40-57, 64 and 65 have been cancelled.

The following is an examiner's statement of reasons for allowance:

The closest prior art, Bosch et al., does not teach nanoparticulate glipizide with at least one surface stabilizer adsorbed on the surface, let alone a spray-dried nanoparticulate glipizide having redispersed effective average particle size of less than 2 microns upon administration to a mammal. The specification shows that this specific nanoparticle glipizide composition results in a C_{max} which is at least 50% greater than the C_{max} exhibits by a non-nanoparticulate glipizide.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN TRAN whose telephone number is (571)272-0606. The examiner can normally be reached on M-F 8:30 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. TRAN/
Primary Examiner, Art Unit 1615